10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? France, Germany, Greece, Netherlands, Norway, Sweden, Switzerland.	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 11 APRIL 2023	
Reference number assigned by the manufacturer FA-2023-015	
FSCA reference number assigned by NCA	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable)	
2. Information on submitter of the report	
Status of Submitters ☒ Manufacturer ☐ Authorized representative within EEA, Switzerland and Turkey ☐ Other (identify the role)	
3. Manufacturer information	
Name Synovis Micro Companies Alliance, Inc. (a subsidiary of Baxter International Inc.)	
Contact name Bradley Schmidt	
Address 439 Industrial Lane	
Postcode AL 35211-4464	City Birmingham
Phone 1-205-941-0111 / 1-205-510-3318	Fax 1-205-941-1522
E-mail bradley_schmidt@baxter.com	Country USA
4. Authorized representative information	
Name Baxter Deutschland GmbH	
Contact name Stéphane Marblie	
Address 4 Edisonstrasse	

Postcode 85716	City Unterschleißheim
Phone +32 475419006	Fax +32 475419006
E-mail complaints_europe@baxter.com	Country Germany
5. National contact point information	
National contact point name BAXTER BELGIUM SPRL	
Name of the contact person APRIL VAN DE MIEROOP	
Address	
Postcode 7860	City LESSINES
Phone	Fax
E-mail FCA_BeNeLux@baxter.com	Country BELGIUM
6. Medical device information	
Class ☐ AIMD Active implants ☒ MDD Class III ☐ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I	 ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code 44814
Nomenclature text: Nerve guide, bioabsorbable, synthetic	
Commercial name/brand name/make NEUROTUBE, 02X40,RP, CE	
Model number	Catalogue number 531101240010 (GEM0240NT)
Serial number(s)	lot/batch number(s) 19012112
Device Manufacturing date: 21 Jan 2019	Expiry date: 31 Dec 2023
Software version number (if applicable)	
Accessories/associated device (if applicable)	
Notified body (NB) ID- number 2797	
7. Description of FSCA	
Background information and reason for the FSCA Baxter Healthcare Corporation is issuing a Recall to the user level for the NEUROTUBE Lot number 19012112 due to the product being brittle and potentially crumbling upon handling or being removed from its package.	
Description and justification of the action (corrective/preventive) A brittle or crumbling NEUROTUBE could lead to delay in therapy, insufficient therapy and/or additional mechanical stress to patient tissue(s). The harm to the patient can vary from transient symptoms that may require	

medical and/or surgical intervention, to more permanent impairment. However, the defect is most likely to be noticed prior to patient use. Baxter has not received any reports of serious injury related to this issue.

Advice on actions to be taken by the distributor and the user

- Locate and remove the affected product.
- Contact Baxter to arrange for return and credit.
- Complete the customer reply form and return it to Baxter
- Forward a copy of this communication If products are distributed to other facilities or departments within your institution

Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English	Draft
FSN in national language	Final
Others (please specify):	

Time schedule for the implementation of the different actions

Implemented on**: 04 APRIL 2023**
Local target closure date: **to be provided once available**

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

Within EEA, Switzerland and Turkey:

AT	BE	BG	CH	CY	CZ	☒ DE	DK	EE	ES
FI	FR	GB	GR	HU	IE	IS	IT	LI	LT
LU	LV	MT	NL	NO	PL	PT	RO	SE	SI
SK	TR	HR							

☐ All EEA, Candidate Countries, Switzerland HA201165 and Turkey

Others:

8. Comments

I affirm that the information given above is correct to the best of my knowledge.
…

Date 11/04/2023

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person